### 10/589562

## JAP11 Rec'd PCT/PTO 16 AUG 2006

PATENT 32860-001072/US

#### IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant(s):

Klaus ABRAHAM-FUCHS et al.

Int'l Application No.:

PCT/EP2005/050401

Application No.:

NEW

Filed:

August 16, 2006

For:

METHOD FOR VERIFYING THE FEASIBILITY OF A

MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR

**PATIENTS** 

# INFORMATION DISCLOSURE STATEMENT (SUBMISSION CONCURRENT WITH THE FILING OF A NEW PATENT APPLICATION)

Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314 Mail Stop PCT August 16, 2006

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

### I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications, or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

#### II. COPIES

Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each
publication or that portion which caused it to be listed; and (iii) all other information
or that portion which caused it to be listed.

This application is a National Phase of a PCT application. Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should be forwarded from the International Search Authority. If copies are needed, please contact the undersigned.

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$\boxtimes$	U.S. p Form foreign	atents of 1449 au n patent	the present application is being filed after June 30, 2003, no copies of the ts or U.S. patent application publications which are listed on the attached of are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any ent documents or non-patent literature listed on the attached Form 1449 are erewith.					
III.			CPLANATION OF THE RELEVANCE tone box)					
	a.		DOCUMENTS IN THE ENGLISH LANGUAGE					
			Some of the attached patents, publications, or other information in the English language do not require a statement of relevancy.					
	b.	$\boxtimes$	DOCUMENTS NOT IN THE ENGLISH LANGUAGE					
			A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:					
			Many of the documents have been discussed in the PCT Search Report, the PCT Preliminary Examination Report, and/or throughout the specification. The PCT Search Report and PCT Preliminary Examination Report, along with a German translation aid translating key terms into English, indicate the degree of relevance found by the PCT Office, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).					
	c.	$\boxtimes$	ENGLISH LANGUAGE SEARCH REPORT					
			An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).					
	d.		OTHER					
			The following additional information is provided for the Examiner's consideration.					
			Applicant encloses a copy of the German Office Action issued on December 14, 2005 in the corresponding German priority application, namely DE 10 2004 052 547.1.					
	e.		EQUIVALENCY DOCUMENTS					

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e. [	] EQUI	VALENCY DOCUMENTS							
	<u>FEES</u>								
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the undersigned	. If it is det det det det de	any questions concerning this IDS, he/she is requested to contact termined that this IDS has been filed under the wrong rule, the this IDS under the proper rule and charge the appropriate fee to 0.							
replies, to charg	If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of ime fees.								
		Respectfully submitted,							
		HARNESS, DICKEY & PIERCE, P.L.C.							
		By: Donald J. Daley, Reg. (No. 34,313)							
DJD:dpg		P.O. Box 8910 Reston, Virginia 20195 (703) 668-8000							
Enclosures:		Form PTO-1449(s) Documents International Search Report (PCT/ISA/210 and PCT/ISA/220) International Preliminary Examination Report (PCT/IPEA/416 and PCT/IPEA/409)							

Other: German Translation Aid

Fee

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PTO/SB/08a (05-03) Approved for use through 04/30/2003. OMB 0651-0031

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Substitute	for form 1449A/PTC	)			Complete if Known
				Application Number	NEW
INFO	RMATION	DIS	CLOSURE	Filing Date	8-16-206
STAT	EMENT B	Y A	PPLICANT	First Named Inventor	Klaus Abraham-Fuchs
				Art Unit	Unkaum
(	use as many shee	ets as i	necessary)	Examiner Name	Clakenus
Sheet	1	of	2	Attorney Docket Number	32860-001072/4s

	U.S. PATENT DOCUMENTS								
Examiner Cite No.1		Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevan Passages or Relevant Figures Appear				
	1	US- 20030212579 A1	11-13-2003	Brown et al. (Inventors)					
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	FOREIGN PATENT DOCUMENTS						
F	Cite No.1	0	Foreign Patent Document	Name of Patentee or	Pages, Columns, Lines, Where Relevant	-12-	
Examiner Initials*		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	Т <sup>6</sup>	
	2	WO 97/28445	08-07-1997	Smithlike Beecham Corporation			
	3	WO 01/55942 A1	08-02-2001	Acurian, Inc.			
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Examiner Signature	Date Considered	·

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Substitute	for form 1449A/PTO			Complete if Known		
INIEO		<b>-</b> 10		Application Number	NEW	
			CLOSURE	Filing Date	8-16-06	
STAT	EMENT BY	AF	PPLICANT	First Named Inventor	Klaus Abraham-Fuchs	
				Group Art Unit	Claken	
(us	se as many sheets	as ne	ecessary)	Examiner Name	Unk again	
Sheet	2	of	2	Attorney Docket Number	32860-001022/45	

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>				
	4	N.H.G.Holford et al.: « Simulation of Clinical Trials », Annual Review of Pharmacology and Toxicology, Vol.40, 2000, pp. 209 – 234, XP002340187					
	5	Pharsight: "Trial-Simulator", Produktprospekt, Mountainview, USA, 2002					
	-						

ſ	Examiner	Date	
l	Signature	Considered	*

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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